ANNEXURE II

List of Raw Materials

S.No	Product	LIST OF RAWMATERIAL
1	Frusemide	Lasamide
		FFA
		$NaHCO_3$
		DMSO
		Lye 48%
		MDC
		Carbon
		H_2SO_4 50%
		Soda ash
		IPA 97%
		Acetic acid 50%
		Spent carbon
2	Glibenclamide	β -PEA
		AC_2O
		Sodium
		Bicarbonate
		MDC
		CSA
		Ammonia 20%
		Aq.Sodium Hydroxide 22.74% w/w
		Ammonia chloride
		Chloro methyl Ester
		Potassium carbonate
		Methanol
		Aq.Hydrochloro (20%)
		CP flakes 90%
		IPA
		CIC
		Acetone
		Aq. Sodium hydroxide (20%)
		Conc. HCl 30%
		CS flakes
3	Glipizide	5 MPCA
		Methanol
		Conc. H_2SO_4
		Soda ash
		MDC
		AEBS
		MeOH
		K2CO3

		H2SO4
		KOH
		Acetone
		CIC
		MDC
		Carbon
		HCl
		Ammonia
		Carbon
		Acetic acid
4	Lovastatin	Dextrose
		Milk powder
		Sugar
		Soyameal
		MgSo4
		Citric Acid
		Sodium Acetate
		Yeast extractor
		Glycerol
		Caustic soda
		Calcium carbonate
		Soya oil

Annexure III

Process description and process flow sheets of the products

FRUSEMIDE

BRIEF MANUFACTURING PROCESS

STAGE –I : Frusemide Technical

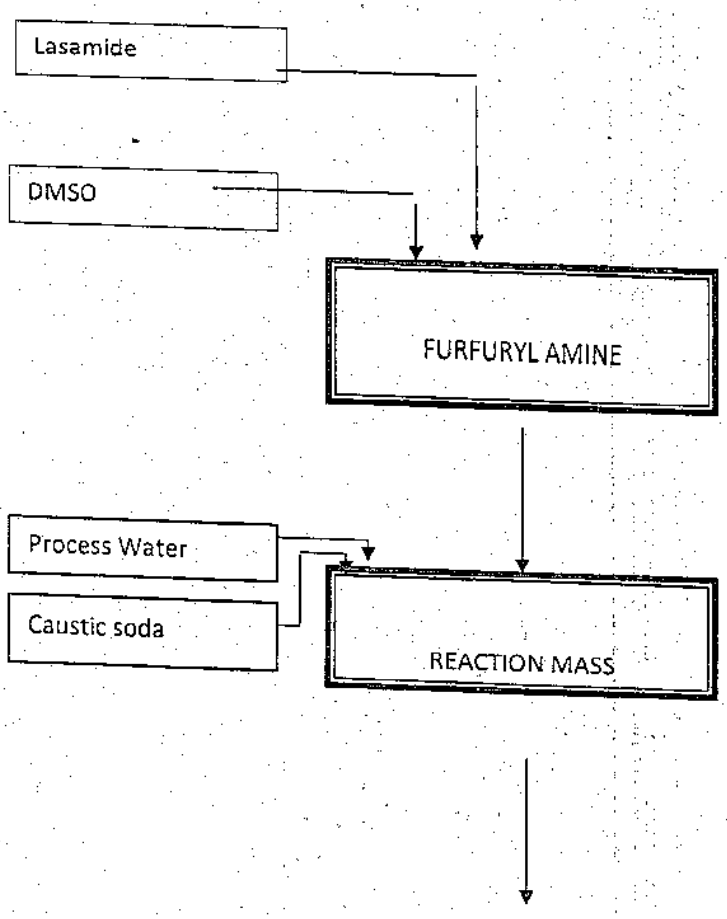
Lasamide is condensed with furfuryl amine in the presence of DMSO and water, sodium hydroxide solution is added to dissolve the material. To the above dissolved solution carbon is added, filtered and the pH of the filterate is adjusted to …….. with dilute sulfuric acid. The mass is centrifuge to get the frusemide technical.

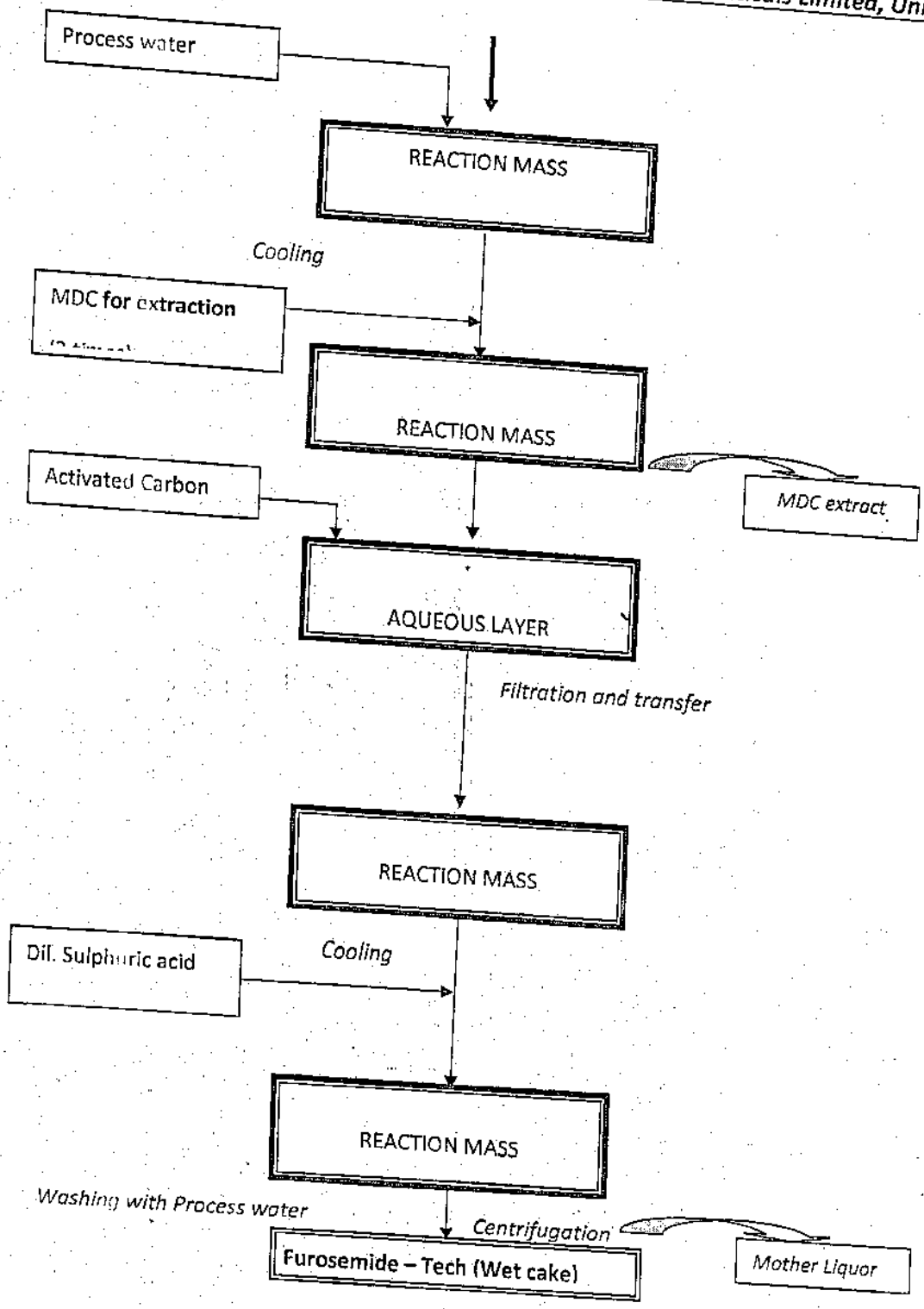
STAGE –II B : Frusemide Pharma

The Frusemide technical is converted to sodium salt and is dissolved treated with carbon, filtered and the filterate of pH is adjusted to 4. With Acetic acid solution. The product is centrifuged and dried to get frusemide Pharma.

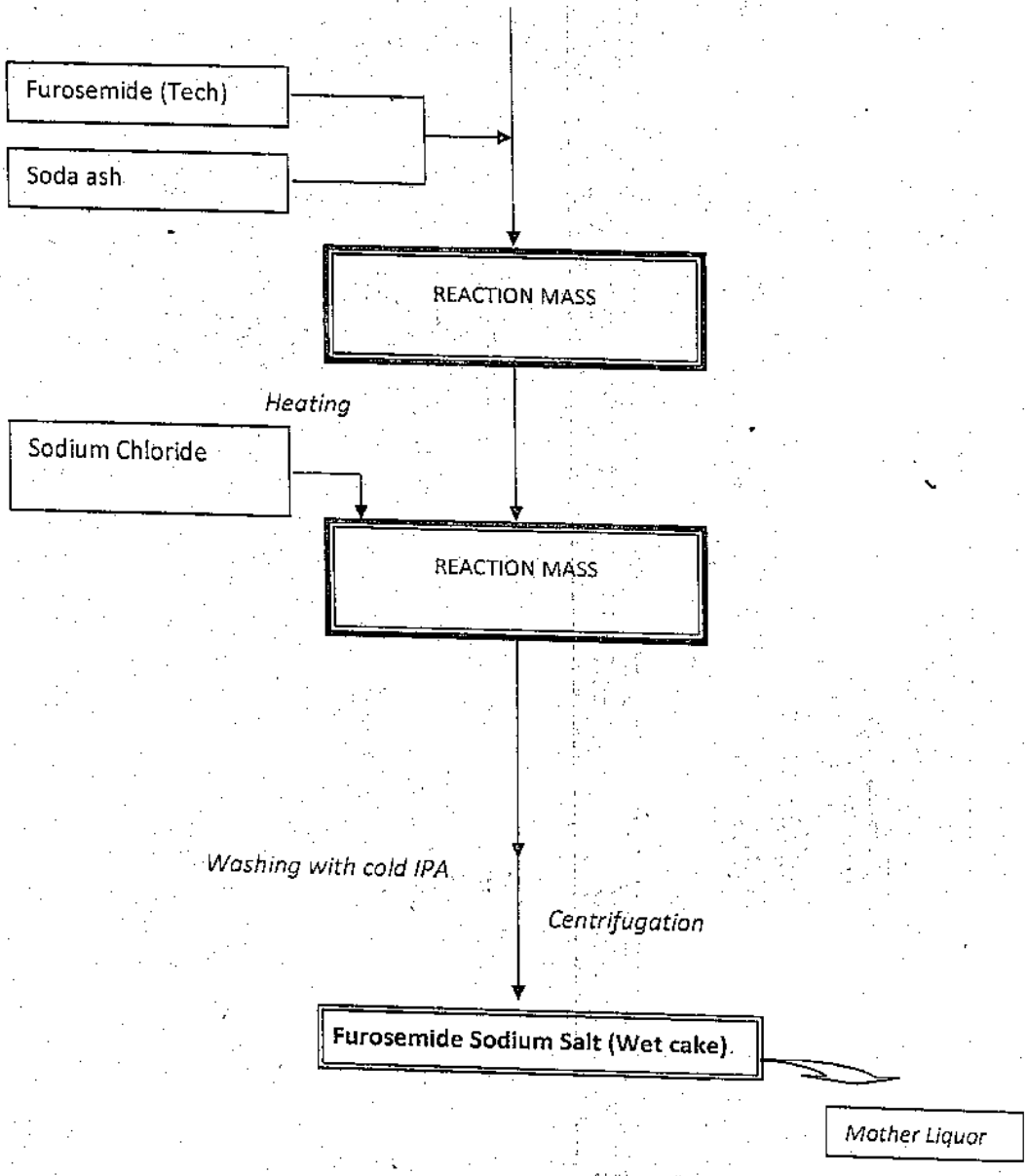
FLOW CHART FOR FUROSEMIDE

Stage-I : FUROSEMIDE - TECHNICAL

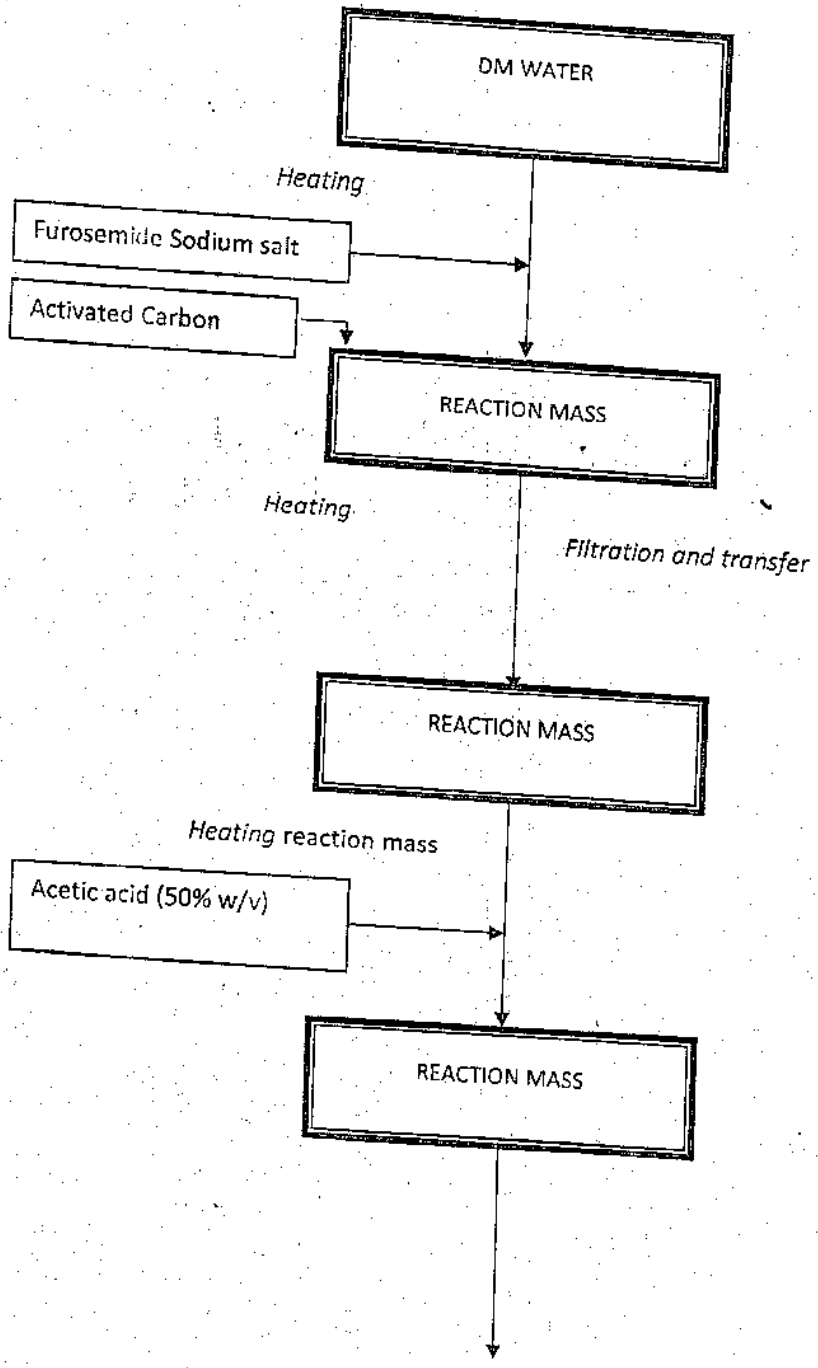


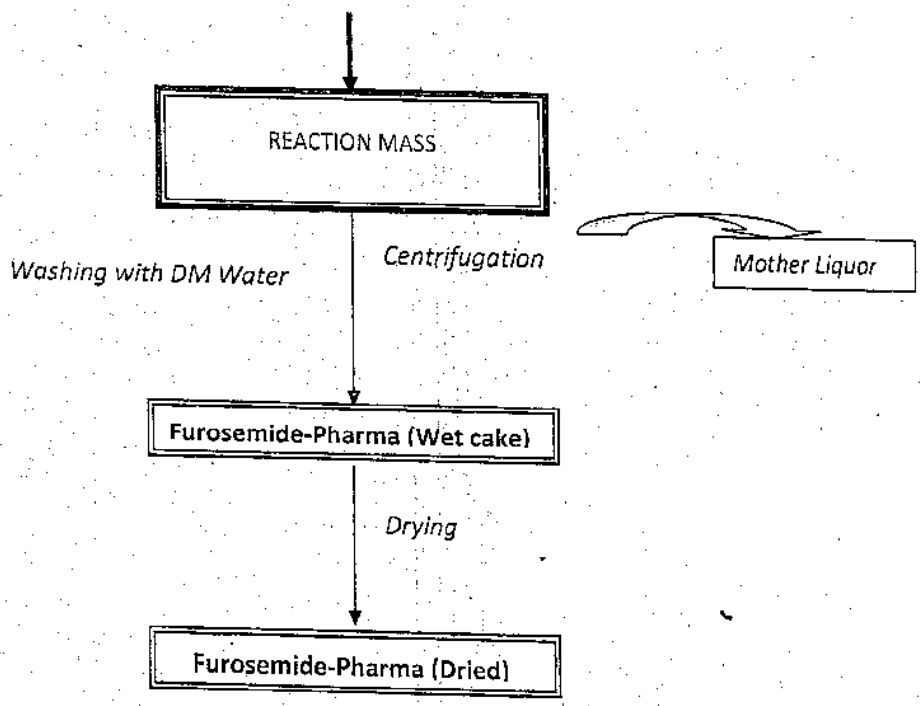

Process water
REACTION MASS
Cooling
MDC for extraction
REACTION MASS
MDC extract
Activated Carbon
AQUEOUS LAYER
Filtration and transfer
REACTION MASS
Dil. Sulphuric acid
Cooling
REACTION MASS
Washing with Process water
Centrifugation
Furosemide – Tech (Wet cake)
Mother Liquor

Stage-II: FUROSEMIDE SODIUM SALT



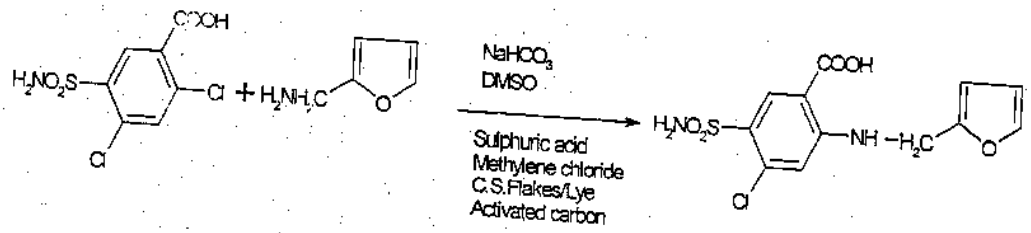
Stage-III: FUROSEMIDE – PHARMA




REACTION MASS
Centrifugation
Mother Liquor
Washing with DM Water
Furosemide-Pharma (Wet cake)
Drying
Furosemide-Pharma (Dried)

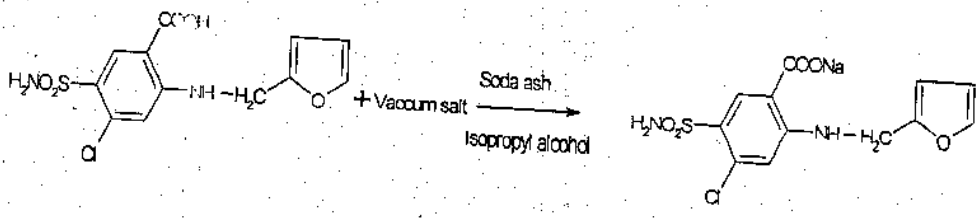
REACTION SCHEME FOR FUROSEMIDE

STAGE – I: FUROSEMIDE TECHNICAL



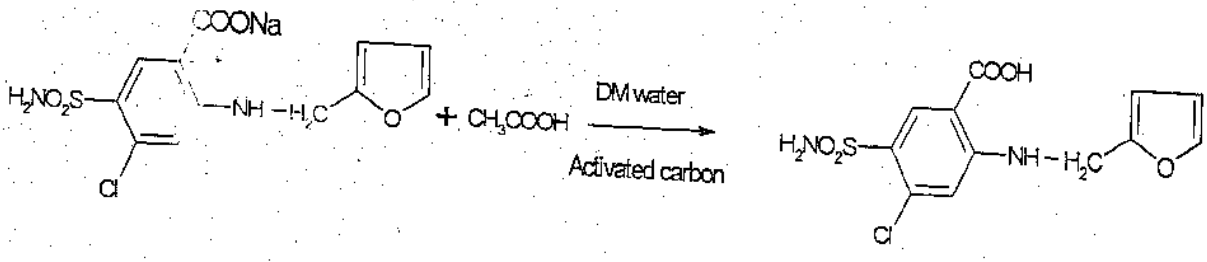
Lasamide Furfurylamine Furosemide Technical

STAGE –II: FUROSEMIDE SODIUM SALT



Furosemide Technical Furosemide Sodium Salt

STAGE –III: FUROSEMIDE PHARMA



Furosemide Sodium Salt Acetic acid Furosemide Pharma